Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Examining the efficacy of the Program for the Education and Enrichment of Relational Skills (PEERS) in improving the social function of adolescents with autism spectrum disorder

Protocol summary

Study aim
-Translation and localization of the Program for the Education and Enrichment of Relational Skills (PEERS) for children and adolescents with autism spectrum disorder (ASD) - Investigating the effectiveness of the PEERS in improving the social functioning of patients with ASD - Preparing a manual for teaching communication skills to adolescents with ASD and their caregivers

Design
A clinical trial with the control group, randomized, on 30 patients. The Simple randomization method is used.

Settings and conduct
Day center of Roozbeh hospital

Participants/Inclusion and exclusion criteria
Age between 12 and 18 years Diagnosis of ASD verbal IQ above 70 No present comorbidity with acute phases of bipolar or psychotic disorders

Intervention groups
The experimental intervention will include 14 sessions of training and strengthening social skills for adolescents with ASD, as well as parallel group sessions for a member of their family. This program is a social skills intervention and addresses elements of social functioning for adolescents such as two-way conversation skills, making friends, using appropriate humor, managing rejection, bullying, or gossiping. Social skills are taught using cognitive behavioral therapy techniques.

Main outcome variables
Improving social interaction and communication in adolescents with ASD

General information

Reason for update

Acronym
PEERS

IRCT registration information
IRCT registration number: **IRCT20230610058443N1**
Registration date: **2023-07-18, 1402/04/27**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-18, 1402/04/27**
Update count: **0**

Registration date
2023-07-18, 1402/04/27

Registrant information

Name
Najmeh Tavakolian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 5541 9151

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tavakoliann@farabi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-06, 1402/04/15

Expected recruitment end date
2024-07-05, 1403/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Examining the efficacy of the Program for the Education and Enrichment of Relational Skills (PEERS) in improving

the social function of adolescents with autism spectrum disorder

Public title
Effect of Program for the Education and Enrichment of Relational Skills (PEERS) for adolescents with Autism Spectrum Disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed diagnosis of autism with ADOS Verbal IQ above 70 Informed consent for 14 weekly sessions and doing tasks A family member who is cooperative to participate in parallel sessions No present comorbidity with acute phases of bipolar or psychotic disorders
Exclusion criteria:
Not participating in more than 3 sessions emergence of acute psychiatric symptoms (aggression, psychosis, suicidal thoughts)
Age
From **12 years** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization is performed. It is an individual randomization unit. The number of groups was set at 2. Group 1 case name and group 2 placebo name were determined. Then the software determined which number is in the case group and which number is in the placebo group. The numbers were matched with an Excel file containing the patients' names, thus identifying the case and control groups. Forty adolescent patients with autism spectrum disorder are numbered from 1 to 30 in the Excel file. Then, 30 patients were entered into the Random Allocation software. The number of groups is set at 2. Group 1 case name and group 2 control name are determined. Then the software determined which number is in the case group and which number is in the control group. The numbers are matched with an Excel file containing the patients' names, thus identifying the case and control groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran university of medical sciences
Street address
Roozbeh hospital, south Kargar, Tehran
City
Tehran
Province
Tehran
Postal code
1333715914
Approval date
2023-03-05, 1401/12/14
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.833

Health conditions studied

1

Description of health condition studied
Autism spectrum disorder (ASD)
ICD-10 code
F84.0
ICD-10 code description
Autistic disorder

Primary outcomes

1

Description
Social Interaction and relationship in adolescents with ASD
Timepoint
before intervention and 14 and 28 weeks after intervention
Method of measurement
Social Skills Improvement System, Social Responsiveness Scale, Friendship Quality Scale, The Quality of Play Questionnaire, Test of Adolescent Social Skills Knowledge.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 14 weekly sessions (90 min) of PEERS and parallel sessions for family members
Category
Treatment - Other

2

Description
Control group: waiting list. Adolescents with ASD who do not receive any nonpharmacologic treatment during the implement of PEERS for intervention group.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh hospital
Full name of responsible person
Najmeh Tavakolian
Street address
Roozbeh hospital, south kargar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotuhi
Street address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Research Center for Cognitive and Behavioral Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Najmeh Tavakolian
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available